

Serial No.: 09/182,102
Filed: October 27, 1998

19. (Twice Amended) A method of identifying the Rad51 genotype of [an] a human individual comprising determining all or part of the sequence of at least one Rad51 gene of said individual and comparing said sequence to a known human Rad51 gene.

21. (Twice Amended) A method according to claim 19 [20] wherein a difference in the sequence between the Rad51 gene of said individual and said known Rad51 gene is indicative of a disease state or a propensity for a disease state, and wherein said difference in the sequence of the Rad51 gene in the individual results in aberrant Rad51, and wherein said disease state is selected from the group consisting of Xeroderma pigmentosum Type A, Xeroderma pigmentosum Type F, and cancer.

Remarks

Claims 18, 19 and 21 are pending. An appendix of the claims as proposed to be amended is attached for the Examiner's convenience.

Applicants respectfully request that the amendments be entered. Applicants believe the amendments place the claims in condition for allowance and at least in better condition for appeal.

The amendments were made to expedite prosecution of this case. Applicants expressly reserve the right to pursue the subject matter of the claims as originally filed in other pending applications.

Support for the amendments to Claims 18 and 19 is found throughout the specification, including on page 10, lines 17 and 20. Support for the amendment to Claim 21 is also found throughout the specification, including on page 38, line 22 and page 33, lines 5-20.

No new issues are raised by the amendments. Specifically, regarding Claims 18 and 19, the Examiner has already considered the issue of "species of organisms" as discussed in the Final Office Action on page 4, paragraph 10. Regarding Claim 21, the Examiner has already considered whether the specification shows a correlation between aberrant Rad 51 and disease states (see page 2, paragraph 4 of the Final Office Action).

Applicants believe that the amendments at least lessen the issues which would be on appeal if the case is not allowed. Entry is respectfully requested.

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The Rejections Under 35 U.S.C. Section 112, First Paragraph

Claim 21 is rejected under 35 U.S.C. Section 112, first paragraph, as "not described in the specification in such a way as to enable one skilled in the art.....to make and/or use the invention". More particularly, the Office Action states that "neither the specification nor the prior art shows any disease that correlates with an aberrant Rad 51 gene". Applicants respectfully traverse.

Applicants respectfully submit that aberrant Rad 51 is correlated with disease states. Support for the correlation between nucleotide excision repair defective cells such as those in individuals suffering from the recessive heredity disorder Xeroderma pigmentosum (XP) is shown in Example 2, including on page 38, line 22. Support for the correlation between aberrant Rad 51 and cancer is shown on page 33.

Provided with the specific examples in the specification, the skilled artisan would find a correlation between disease states and aberrant Rad51. In addition to the specific disease states demonstrated in the application, the application discloses a number of Rad51 functions, which in conjunction with the specific examples demonstrate that aberrant Rad51 would result in a disease state. For example, changes in biological function of Rad51 include altered nucleic acid binding, filament formation, DNA pairing (i.e. D-loop formation), strand-exchange, strand annealing or recombinagenicity (page 9, lines 14-28, page 17, lines 1-17). Thus, provided with the present specification, the skilled artisan would find the assertions made by Applicants reasonable, and would expect to be able to practice the claimed invention. Applicants, therefore, submit that Claim 21 is enabled and request that the rejection be withdrawn.

The Rejections Under 35 U.S.C. Section 102

Claims 18 and 19 are rejected under 35 U.S.C. Section 102(b) as anticipated by Ogawa, et al., RecA-like Recombination Proteins in Eukaryotes: Functions and Structures of RAD51 genes, Cold Harbor Symposium on Quantitative Biology, vol. 43, pages 567-576 (1993) (Ogawa). Applicants respectfully traverse.

To anticipate, each and every element must be disclosed. Ogawa does not disclose a method for determining whether a mammalian cell contains a mutant Rad51 gene. Moreover, Ogawa does not disclose a method for identifying Rad51 genotypes of human


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individuals. Therefore, Ogawa does not disclose each element of the claimed invention. Since Ogawa does not anticipate the claimed invention, Applicants request that the rejection be withdrawn.

Applicants submit that all the claims are in condition for allowance and an early notification of such is solicited.

Respectfully submitted,

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APPENDIX:

18. (Twice Amended) A method of determining whether a mammalian cell contains a mutant Rad51 gene comprising determining the sequence of all or part of an endogenous Rad51 gene of a mammalian cell and comparing said sequence to a known mammalian Rad51 gene.

19. (Twice Amended) A method of identifying the Rad51 genotype of [an] a human individual comprising determining all or part of the sequence of at least one Rad51 gene of said individual and comparing said sequence to a known human Rad51 gene.

21. (Twice Amended) A method according to claim 19 [20] wherein a difference in the sequence between the Rad51 gene of said individual and said known Rad51 gene is indicative of a disease state or a propensity for a disease state, and wherein said difference in the sequence of the Rad51 gene in the individual results in aberrant Rad51, and wherein said disease state is selected from the group consisting of Xeroderma pigmentosum Type A, Xeroderma pigmentosum Type F, and cancer.